

Remarks

Reconsideration of this Application is respectfully requested.

I. Status Of The Claims

Claims, 1, 4, 9 and 12 have been amended herein, and new claims 55-70 have been added. Support for the amendment is found in the present specification. No new matter has been added by these amendments.

II. The Rejection Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

At page 3 of the Office Action, the Examiner rejected claims 1-4, 7, 9, 10, 12 and 50-54 under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicants respectfully traverse this rejection. The claimed invention is definite.

With regard to independent claim 1, the Examiner stated:

It is unclear if Applicants intend a ***single polynucleotide*** to encode a single chimeric polypeptide comprising a DNA binding domain, an ecdysone receptor ligand binding domain, a second nuclear receptor ligand binding domain and a transactivation domain or ***a first polynucleotide*** encoding a polypeptide comprising a DNA binding domain and an ecdysone receptor ligand binding domain and ***a second polynucleotide*** encoding a second polypeptide comprising a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain and a transactivation domain or ***a first polynucleotide*** encoding a polypeptide comprising a DNA binding domain, an ecdysone receptor ligand binding domain and a second nuclear receptor ligand binding domain and ***a second polynucleotide*** encoding a polypeptide encoding a transactivation domain or something else entirely.

Office Action at page 3.

With regard to independent claim 9, the Examiner stated:

It is unclear if the receptor complex comprises *a single polypeptide* comprising a DNA binding domain, an ecdysone receptor ligand binding domain, a nuclear receptor ligand binding [sic] and a transactivation domain or *a first polypeptide* comprising a DNA binding domain and an ecdysone receptor ligand binding domain and *a second polypeptide* comprising a second nuclear receptor ligand binding domain and a transactivation domain or some other combination of polypeptides.

Office Action at pages 4-5.

The Examiner also stated:

[T]he only working examples are directed to polynucleotides encoding polypeptides comprising a DNA binding domain, and an ecdyson [sic] ligand binding domain and polynucleotides encoding transactivation domain and a chimeric RXR-USP ligand binding domain. There are no examples, working or prophetic, of polynucleotides encoding, for example, chimeric polypeptides comprising an ecdysone ligand binding domain and a second ligand binding domain.

Office Action at pages 5-6.

In the multiple inducible gene regulation system of independent claims 1 and 9, for each of the orthogonal gene regulation systems, the DNA binding domain, the ecdysone receptor ligand binding domain, the nuclear receptor capable of forming a dimer with the ecdysone receptor ligand binding domain, and the transactivation domain operate together as components of a *receptor complex* which regulates the transcription of a gene of interest in response to a ligand that binds to the ecdysone receptor ligand binding domain.

In claim 1, for each of the orthogonal gene regulation systems, the *receptor complex* can be encoded by a single polynucleotide. Alternatively, *components* of the

receptor complex can be encoded by one or more polynucleotides. Support for this is found in original claim 1, which recited "one or more polynucleotides encoding a receptor complex" Pending independent claim 1 recites "*a* polynucleotide encoding a receptor complex comprising" Under controlling Federal Circuit case law, the word "*a*" in a claim that also contains the word "comprising" is construed to mean "at least" or "one or more." *See, e.g., Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023, 43 USPQ2d 1545, 1548 (Fed. Cir. 1997).

Regardless of whether the receptor complex in each of the orthogonal gene regulation systems in the multiple inducible gene regulation system of claim 1 is encoded by one polynucleotide or more than one polynucleotide, claim 1 is definite.

For at least the same reasons, the claims that depend from claim 1 are definite.

In pending independent claim 9, for each of the orthogonal gene regulation systems, the *receptor complex* can be a single polypeptide. Alternatively, *components* of the receptor complex can be encoded by one or more polypeptides.

Regardless of whether the receptor complex in each of the orthogonal gene regulation systems in the multiple inducible gene regulation system of claim 9 is one polypeptide or is more than one polypeptide, the invention of claim 9 is definite.

For at least the same reasons, the claims that depend from claim 9 are definite.

Applicants respectfully request that this rejection be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly addressed. Applicants therefore respectfully request that the Examiner reconsider and withdraw the

presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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